

SOMBRA PLUS CBD 500MG COOL THERAPY- menthol gel
SOMBRA COSMETICS INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Sombra Plus CBD 500MG Cool Therapy

Active Ingredients

Menthol USP 6%

Purpose

Purpose
External Analgesic

Keep out of reach of children

Keep out of reach of children

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with: strains, bruises, and sprains

Warnings

For external use only. Do not use on wounds or damaged skin or with heat source. If you are pregnant or breastfeeding, consult a healthcare professional before use. **When using this product:** Avoid bandaging tightly, avoid contact with eyes, **keep out of reach children.**

Directions

adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily, rub in thoroughly until gel is absorbed, **children under 2 years of age:** consult a doctor.

Inactive Ingredients

aloe barbadensis leaf juice, camellia sinensis (green tea) leaf extract, Cannabidiol (isolate), caprylyl glycol, carbomer, citrus grandis (grapefruit) seed extract, citrus limon (lemon) peel oil, decyl glucoside, glycerin, hamamelis virginiana (witch hazel) leaf extract, phenoxyethanol, purified water, rosa damascena flower water, sodium carbonate, Filipendula ulmaria (queen of the prairie) flower extract, yucca schidigera root extract,

Questions or Comments

1-800-225-3963

Drug Facts

NDC 61577-7500-2

Active Ingredients:

Menthol, USP 6.0%

Purpose:

External analgesic

Uses:

Temporarily relieves minor aches and pains of muscles and joints associated with: ■ strains ■ bruises ■ sprains.

Warnings:

For external use only. Do not use on wounds or damaged skin or with a heat source. If you are pregnant or breastfeeding, consult a healthcare professional before use. When using this product, ■ avoid bandaging tightly ■ avoid contact with eyes ■ Keep out of reach of children.

SOMBRA[®]

PLUS

CBD 500mg

Cool therapy

NET WT. 2 OZ. 56.7 G

natural pain relieving gel

Drug Facts (continued)

Stop use and ask a doctor if: ■ condition worsens ■ symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days.

Directions:

Adults and children 2 years of age and older: ■ apply to affected area not more than 3 to 4 times daily ■ rub in thoroughly until gel is absorbed. Children under 2 years of age: consult a doctor.

Inactive Ingredients:

Aloe Barbadosensis Leaf Juice, Camellia Sinensis (Green Tea) Leaf Extract, Cannabidiol (isolate), Caprylyl Glycol, Carbomer, Citrus Grandis (Grapefruit) Seed Extract, Citrus Limon (Lemon) Peel Oil, Decyl Glucoside, Glycerin, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Phenoxylethanol, Purified Water, Rosa Damascena Flower Water, Sodium Carbonate, Filipendula Ulmaria (Queen of the Prairie) Flower Extract, Yucca Schidigera Root Extract.

Questions or Comments? 1-800-225-3963

SPOT UV KNOCKOUT

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Made in USA • Manufactured by Sombra, Inc.

SOMBRA PLUS CBD 500MG COOL THERAPY

menthol gel

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		TOPICAL	NDC:61577-7500	
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)			MENTHOL	0.06 g in 1 g
Inactive Ingredients				
Ingredient Name				Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)				
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)				
WATER (UNII: 059QF0K00R)				
GRAPEFRUIT SEED OIL (UNII: 598D944HOL)				
GREEN TEA LEAF (UNII: W2ZU1RY8B0)				
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)				
ROSA CENTIFOLIA FLOWER OIL (UNII: H32V31VMWY)				
SODIUM CARBONATE (UNII: 45P3261C7T)				
GLYCERIN (UNII: PDC6A3C0OX)				
WITCH HAZEL (UNII: 101I4J0U34)				
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)				
LEMON OIL (UNII: I9GRO824LL)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
CAPRYLYL GLYCOL (UNII: 00YIU5438U)				
CANNABIDIOL (UNII: 19GBJ60SN5)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-7500-2	56.7 g in 1 JAR; Type 0: Not a Combination Product	11/03/2020	
2	NDC:61577-7500-4	113.4 g in 1 JAR; Type 0: Not a Combination Product	11/03/2020	
Marketing Information				

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/03/2020	

Labeler - SOMBRA COSMETICS INC. (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
SOMBRA COSMETICS INC		097464309	manufacture(61577-7500) , label(61577-7500)

Revised: 10/2020 SOMBRA COSMETICS INC.